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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Takeshi Hagio

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EXAMINER

FERNANDEZ, SUSAN EMILY

ART UNIT

PAPER NUMBER

1651

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/521,622	Applicant(s) HAGIO ET AL.	
	Examiner SUSAN E. FERNANDEZ	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,6,10-27,30-48 and 71 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,6,10-27,30-48 and 71 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The amendment filed March 1, 2010, has been received and entered.

Claims 2-5, 7-9, 28, 29, and 49-70 are canceled.

Claims 1, 6, 10-27, 30-48, and 71 are pending and examined on the merits.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 6, 10-27, 30-48, and 71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dev et al. in view of Porter et al. (US 2,932,128).

Dev et al. teaches "a method for producing a genetically modified plant by introducing a polynucleotide to an intact plant or plant cell(s) via electroporation, in the absence of cell wall-

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degrading enzymes" (abstract). The "plant cell" may be an intact cell of a seed (column 4, lines 15-17), wherein the recitation "intact" signifies that the cell wall is undamaged or untreated (column 4, lines 20-22). The method can be applied to monocotyledonous plants such as corn, wheat, rice, and dicotyledonous plants such as tomato, rapeseed, soybeans, and cabbage (column 6, lines 15-25). Moreover, Dev et al. indicates that "one of skill in the art could determine the appropriate parameters for the leaf type used" (column 8, lines 62-63). For instance, a voltage of 40-50 V/cm for electroporation, which is within the range recited in instant claim 6, is deemed suitable for "soft and thin" leaves (column 8, lines 63-65). Note that the cells can be placed in a cuvette with the plasmid DNA for electroporation (column 12, lines 29-40).

Dev et al. differs from the claimed invention in that it does not disclose that when the plant cell (such as a seed) is with the polynucleotide in a container (such as a cuvette), the container is depressurized to about 0.096 MPa below the atmospheric pressure, prior to putting the seed and the nucleic acid under conditions to induce electroporation.

Porter et al. discloses the inoculation of seeds under conditions of reduced pressure with particulate matter (column 1, lines 17-20). The particulate matter can be bacteria, and the seeds are subjected to reduced pressure while in contact with a liquid suspension of the particulate matter (column 2, lines 9-12). The seeds obtained through the process are intact (column 2, lines 33-36 and 47-49). Moreover, the extent to which the pressure is reduced in the inoculation step may vary considerably (column 2, lines 53-54). For instance, the treatment can be performed under a reduced pressure of about 1.1 inches of mercury (column 2, line 70 through column 3, line 2). A pressure of 1.1 inches of mercury is about 0.0037 MPa. Given that atmospheric pressure, 1 atm, is about 0.10 MPa, a pressure reduced by about 0.096 MPa from the atmospheric

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pressure is about 0.004 MPa. Therefore, Porter et al. teaches a pressure that meets the pressure limitation of instant claims 1 and 27.

At the time the invention was made, it would have been obvious to the person of ordinary skill in the art to have included in the Dev invention a step of depressurizing the container holding the plant cell and polynucleotide prior to or during the electroporation step, when the plant cell is a seed. One of ordinary skill in the art would have been motivated to do this since the step of depressurization of a container holding a plant cell in a liquid suspension of particulate matter results in the inoculation of the seed with particulate matter. Given that particulate matter can enter the seed through depressurization, the seed can be inoculated with matter as small as a nucleic acid. Clearly depressurization would have contributed to introducing polynucleotides into seeds, thus improving the efficiency of the Dev invention. As a pressure of about 0.0037 MPa is suitable for delivering particulate material into a seed, it would have been obvious to have used such a pressure in delivering polynucleotides into seeds. Moreover, the selection of a suitable pressure would have been a matter of routine experimentation, especially considering that Porter et al. indicates that "the extent to which the pressure is reduced in the inoculation step of this process may vary considerably" (column 2, lines 53-54). Thus, instant claims 1, 10-16, 18-22, 27, 30-36, 38-42, 47, 48, and 71 are rendered obvious.

Additionally, there would have been a reasonable expectation of success in transferring nucleic acids into seeds of plants other than those indicated in the Dev invention to yield the predictable result of inoculating such seeds with polynucleotides. Thus, claims 17, 23-26, 37, and 43-46 are rendered obvious.

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Also, the selection of a specific suitable voltage pulse and voltage pulse application directions, including that claimed, would have been an obvious matter of optimization on the part of the artisan of ordinary skill, particularly since Dev et al. teaches that the skilled artisan would determine the appropriate parameters for the leaf type used. Moreover, Dev et al. teaches that electroporation applied at a voltage of 40-50 V/cm, which is within the range recited in instant claim 6, is deemed suitable for the introduction of a polynucleotide into “soft and thin” leaves. Therefore, appropriate parameters for different seeds would also have been determined by the skilled artisan, and a voltage of 40-50 V/cm would have been a suitable starting point for routine experimentation for the selection of a specific voltage pulse. Thus, instant claim 6 is rendered obvious.

A holding of obviousness is clearly required.

Response to Arguments

Applicant's arguments filed March 1, 2010, have been fully considered but they are not persuasive. The applicant asserts that the Porter reference fails to qualify as analogous prior art. However, Porter refers to the inoculation of seeds with material, which fits within the teachings of Dev et al. of inoculating plant cells such as seeds with material that is specifically a polynucleotide. As Porter teaches the inoculation of seeds with bacteria, its teachings can be applied to the inoculation of material smaller than bacteria, including polynucleotides. There would have been reasonable expectation of success that polynucleotides can be inserted into seeds by the methods of Porter et al. given that the methods are suitable for larger material.

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The applicant also asserts that Porter fails to teach placing a seed containing the cell and nucleic acid in a container and depressurizing the container. However, with respect to the presence of the seed in a container, a container would have been required by Porter in order to hold the seed and the liquid suspension is contacted with. With respect to the nucleic acid in the container, this aspect is taught by Dev as the seed and nucleic acid must be held in one place. Furthermore, Dev teaches in Example 1 placing embryos (an example of cells suitable for practice of the Dev invention) placed in a cuvette.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN E. FERNANDEZ whose telephone number is (571)272-3444. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon B Lankford/
Primary Examiner, Art Unit 1651

Susan E. Fernandez
Examiner
Art Unit 1651

sef